



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1896]

Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff; Information Available to Industry; Extension of the Proposal Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of the proposal period.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is extending the proposal period for the “Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff,” published in the *Federal Register* of June 29, 2018. FDA is extending the proposal period to allow interested persons additional time to submit an electronic or written proposal.

DATES: FDA is extending the proposal period on the notice published June 29, 2018 (83 FR 30751). Submit either an electronic or written proposal by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] directly to Tara Gooen Bizjak or Stephen Ripley (see FOR FURTHER INFORMATION CONTACT).

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2109, Silver Spring, MD 20993-0002, 301-796-3257, email: Tara.Gooen@fda.hhs.gov, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration,

10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of June 29, 2018 (83 FR 30751), FDA announced the availability of a notice for industry entitled “Quality Metrics Site Visit Program for Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research Staff.” Interested persons were originally given until August 28, 2018, to submit a proposal to the Quality Metrics Site Visit Program per the notice. The Agency believes that extending the proposal period for an additional 120 days from the date of publication of this notice will allow adequate time for interested persons to submit proposals for FDA’s consideration. The Site Visit Program is to provide experiential and firsthand learning opportunities to FDA staff involved in the development of the FDA Quality Metrics Program and to provide stakeholders with an opportunity to explain the advantages and challenges associated with implementing and managing a robust Quality Metrics Program. The program and information to be included in the proposal are explained more fully in the original notice.

II. Electronic Access

Persons with access to the internet may obtain the information about the FDA Quality Metrics for Drug Manufacturing Program, including this Quality Metric Site Visit Program, at <https://www.fda.gov/drugs/developmentapprovalprocess/manufacturing/ucm526869.htm>.

Dated: August 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

